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EXAMINER	
HAND, MELANIE JO	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/682,460	**Applicant(s)** KADZIAUSKAS ET AL.
	Examiner MELANIE J. HAND	**Art Unit** 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 22 January 2008.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 and 29-44 is/are pending in the application.

4a) Of the above claim(s) 6,8,12,13,19,21,34,38 and 40 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1~5,7,9-11,14-18,20,22-24,29-33,35-37,39,41-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 22, 2008 have been fully considered but they are not persuasive.

2. With respect to arguments regarding the rejection of claims 1-4 and 14-17 as unpatentable over Urich and Dillon: Applicant argues that Urich does not teach or suggest a tubular member configured to enhance flow of fluid into an irrigation lumen upon clearing of the occlusion 34. To support this argument applicant states that Urich teaches a surge suppressor as the tubular member that prevents surge of fluid from an eye when an occlusion breaks. While this is true, the surge suppressor is preventing a surge or enhancement of flow of fluid from the eye in the aspiration lumen, not the irrigation lumen. Therefore, Urich is not teaching away from a tubular member to enhance flow of fluid into the irrigation lumen. Applicant cites col. 3, lines 10-12 in further support of this, which again only discusses preventing a sharp surge of fluid from the eye which would not be flowing through the irrigation lumen, thus the cited passage is irrelevant to applicant's argument. Applicant further argues that Urich does not teach or suggest an expandable wall configured to expand during occlusion of an aspiration lumen. Applicant is reminded of the customary way in which the phrase "configured to" is typically interpreted by the Office, i.e. that something that is capable to expand is sufficient to anticipate the claim as such expansion is not positively recited. Therefore, the tubular member in the form of surge suppressor 24 having an expandable wall 26 that expands immediately after an occlusion 34 is dislodged meets this limitation because wall 26 is configured to expand upon accumulation of fluid within said tubular member inasmuch as it is capable of doing so. Since the expansion is not positively recited and the wall is capable of the expansion as claimed during occlusion, the

fact that Urich teaches that the wall collapses does not constitute a teaching away from the claimed invention. Further, this collapse does not happen immediately, rather it is prompted by a sufficient accumulation of increased pressure form fluid supply bottle 18 and sufficient decrease in pressure that accumulates shortly after the occlusion occurs. Therefore, the wall can still expand after the increase in fluid pressure upstream from the occlusion that is capable of causing expansion of the wall, but prior to the collapse that Urich is referring to.

Applicant argues that neither Urich nor Dillon teaches or suggests a variant of the device of Urich to prevent excessive flow of irrigation solution to the eye that would motivate one of ordinary skill in the art to provide a tubular member disposed along the irrigation line of Urich. This is not persuasive because both of the prior art references of Urich and Dillon concern themselves with intraocular surgery and the irrigation and aspiration of excess fluid in the eye (e.g. via vitrectomy as taught by Dillon) to prevent cataracts. Urich teaches an irrigation line channeling irrigation fluid to an eye during surgery, and Dillon teaches that following the vitrectomy, the vitreous is usually replaced by irrigation solution that contains a much higher partial pressure for oxygen than the vitreous body that was removed. Dillon teaches that this exposes the lens of the eye to an extremely high level of oxygen and oxygen is a known hazard to lens transparency. (‘814, ¶0053) Further, such irrigation solution can disrupt the oxygen pressure gradient between the posterior and anterior chambers of the eye, causing cataracts. (‘814, ¶0053) Since the prior art of Urich is concerned with preventing or treating cataracts (Col. 1, lines 11-13), one of ordinary skill in the art would thus certainly be motivated to modify the device of Urich in light of the teachings of Dillon to include a tubular surge suppressor in the irrigation line as well to prevent excess flow of irrigation fluid, as such a modification would ensure the proper administration of irrigation solution to the eye at all times to mitigate the risk of new cataracts forming.

As to applicant's argument that a surge suppressor in the irrigation line would not result in a collapse of wall 26 that would suppress the flow of irrigation fluid as taught by Urich for the suppressor in the aspiration line, Urich teaches that fluid can either be forced out of chamber 28 by squeezing wall 26, an action that would also function to pinch or shut off flow through the irrigation line temporarily. Since this action can be performed at the will of the user, the suppressor would in fact be effective to prevent excess flow of irrigation fluid to the eye as desired.

3. Applicants' arguments with regard to dependent claims 5, 7, 9-11, 18, 20, 22-24, 29-33, 35, 37-39 and 41-44 have been fully considered but are not persuasive as Applicants' arguments depend entirely on Applicants' arguments regarding the rejection of claim 1, which have been addressed *supra*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814).

With respect to **claim 1:** Urich teaches an infusion source for a ocular surgery having a needle in the form of infusion sleeve 14 having sharp tip 12 mounted coaxially therein with at least an irrigation lumen defined by the inner wall of sleeve 14 comprising a fluid supply in the form of gravity bottle 18 (Col. 2, lines 14-23); an irrigation line 16 interconnecting said fluid supply 18 and said irrigation lumen defined by sleeve 14 (Col. 4, lines 21-23). A tubular member in the form of surge suppresser 24 is disposed along an aspiration line 20, as part of and in fluid communication with said aspiration line 20 in that it is located inside of line 20, and an aspiration lumen in the form of an inner channel (not shown) within tip 12. The tubular member 24 has a collapsible flexible wall 26, which is considered herein to also be expandable due to its flexibility. The tubular member 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid to enhance flow of fluid into said irrigation lumen upon clearing of the occlusion, inasmuch as “configured to” is interpreted as meaning “capable of”. That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (‘448, Col. 2, lines 25-37)

Urich does not teach that the tubular member 24 is disposed along said irrigation line 16 as part of and in fluid communication with said irrigation line 16 and said irrigation lumen 14. However, Urich teaches that the flow-limiting device of said tubular member prevents a surge of flow of aspiration that could result in excessive vacuum pressure at the surgery site and potential collapse of the anterior chamber of the eye. Dillon teaches that it is known that changes to the partial pressure of oxygen in the eye is a hazard to lens transparency and can cause cataracts. Thus, since the device of Urich is used in intraocular surgeries to remove cataracts, it would be obvious to one of ordinary skill in the art to modify the device of Urich such that a flow-limiting member is disposed along the irrigation line as part of and in fluid communication with said irrigation line and said irrigation lumen to prevent excessive flow of irrigation solution to the surgery site as taught by Dillon. (‘814, ¶0053)

With respect to **claim 2:** The tubular member 24 taught by Urich is disposed proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. (‘448, Col. 1, lines 10-14, Col. 4, lines 43-45)

With respect to **claim 3:** The tubular member 24 taught by Urich is disposed in parallel fluid communication with said irrigation line 16 and irrigation lumen 14. (‘448, Fig. 1)

With respect to **claim 4:** The tubular member wall 26 taught by Urich is formed from silicone, an elastomeric material, and is thus elastic. (‘448, Col. 2, lines 41-44)

With respect to **claim 14:** Urich teaches an infusion source comprising: a surgical instrument 11 considered herein to be a handpiece inasmuch as Urich teaches that the instrument 11 has a tip 12 for insertion into the cornea for use in a known emulsification procedure that cannot be accomplished with a non-handheld device. The handpiece 11 has a needle in the form of sleeve 14 with sharp tip 12 positioned therein at an end of said sleeve 14 with an irrigation lumen defined by the inner wall of sleeve 14 (Col. 2, lines 14-23); a fluid supply in the form of gravity bottle 18 (Col. 2, lines 23-25); an irrigation line 16 interconnecting said fluid supply 18 and said irrigation lumen 14 (Col. 2, lines 23-27); and a tubular member in the form of surge suppresser 24 disposed along said aspiration line 20 and in fluid communication with an aspiration line 20 and an aspiration lumen in the form of an inner channel (not shown) within tip 12. Tubular member 24 has a collapsible flexible wall 26, which is considered herein to also be expandable due to its flexibility. The tubular member 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid to enhance flow of fluid into said irrigation lumen upon clearing of the occlusion, inasmuch as “configured to” is interpreted as meaning “capable of”. That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (Col. 2, lines 25-37)

Urich does not teach that the tubular member 24 is disposed along said irrigation line 16 as part of and in fluid communication with said irrigation line 16 and said irrigation lumen 14. However, Urich teaches that the flow-limiting device of said tubular member prevents a surge of flow of aspiration that could result in excessive vacuum pressure at the surgery site and potential collapse of the anterior chamber of the eye. Dillon teaches that it is known that changes to the partial pressure of oxygen in the eye is a hazard to lens transparency and can cause cataracts. Thus, since the device of Urich is used in intraocular surgeries to remove cataracts, it would be obvious to one of ordinary skill in the art to modify the device of Urich such that a flow-limiting member is disposed along the irrigation line as part of and in fluid communication with said irrigation line and said irrigation lumen to prevent excessive flow of irrigation solution to the surgery site as taught by Dillon. (‘814, ¶0053)

With respect to **claim 15:** The tubular member 24 taught by Urich is disposed proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. (‘448, Col. 1, lines 10-14, Col. 4, lines 43-45)

With respect to **claim 16:** The tubular member 24 taught by Urich is disposed in parallel fluid communication with said irrigation line 16 and irrigation lumen 14. (‘448, Fig. 1)

With respect to **claim 17:** The tubular member wall 26 taught by Urich is formed from silicone, an elastomeric material, which is an elastic material. (‘448, Col. 2, lines 41-44)

6. Claims 5, 7, 9-11, 18, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814) as applied to claims 1-4 and 14-17 above, and further in view of Mackool (U.S. Patent No. 5,084,009).

With respect to **claim 5:** The combined teaching of Urich and Dillon does not teach a sheath disposed around an expandable elastic wall, e.g. wall 26 taught by Urich. Mackool teaches a phacoemulsification (hereafter, “phaco”) needle 106 having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle 106. Mackool teaches that the inner sheath 108 prevents the outer silicone sheath from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12. The tubular member of the combined teaching of Urich and Dillon and Mackool comprises a sheath such as external sheath 102 taught by Mackool, disposed around an expandable wall such as wall 26 taught by Urich. (‘009, Col. 5, lines 48-57, col. 6, lines 1-5)

With respect to **claim 7:** The sheath of the combined teaching of Urich and Dillon and Mackool is comprised of silicone (as taught by Mackool), which is a flexible material, as Mackool teaches that the silicone sheath 102 collapses. Thus, the sheath is flexible. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 5.

With respect to **claim 9:** With regard to the limitation “the sheath and expandable wall of the device of Urich and Dillon and Mackool are integrally molded”, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 10:** The device of Urich and Dillon and Mackool does not explicitly teach a further comprising a plurality of expandable walls molded in a spaced apart relation within said sheath. However, since Mackool teaches that the inner sheath 106 (e.g. expandable wall 26 taught by Urich) prevents the external sheath 102 from collapsing, multiple sheaths would provide additional protection against collapse of the outer sheath, thus it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Mackool so as to further comprise a plurality of expandable walls molded in a spaced apart relation within said sheath. Further, it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to the limitation “molded in a spaced apart relation”, such limitation constitutes product-by-process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 11:** The expandable wall 26 taught by Urich and Dillon is comprised of silicone walls, an elastomeric material, and is thus elastic. The sheath 102 taught by Mackool is also silicone and is thus also formed from an elastic material. The said expandable walls fairly suggested by Urich and Dillon and Mackool are thus elastic. Mackool shows in Fig. 9 an inner sheath 108 that is relatively thin compared with the thickness of the sheath 102. Thus the combined teaching of Urich and Dillon and Mackool fairly suggest an inner sheath, or expandable wall, that is relatively thin compared with the thickness of an outer sheath, such as sheath 102. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 5.

With respect to **claim 18:** The combined teaching of Urich and Dillon does not teach a sheath disposed around an expandable elastic wall, e.g. wall 26 taught by Urich. Mackool teaches a phacoemulsification (hereafter, “phaco”) needle 106 having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle 106. Mackool teaches that the inner sheath 108 prevents the outer silicone sheath from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12. The tubular member of the combined teaching of Urich and Dillon and Mackool comprises a sheath such as external sheath 102 taught by Mackool, disposed around an expandable wall such as wall 26 taught by Urich.

With respect to **claim 20:** The sheath of the combined teaching of Urich and Mackool is comprised of silicone (as taught by Mackool), which is a flexible material, as Mackool teaches that the silicone sheath 102 collapses. Thus, the sheath is flexible. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 18.

With respect to **claim 22:** With regard to the limitation “the sheath and expandable wall of the device of Urich and Dillon and Mackool are integrally molded”, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 23:** The device of Urich and Dillon and Mackool does not explicitly teach a further comprising a plurality of expandable walls molded in a spaced apart relation within said sheath. However, since Mackool teaches that the inner sheath 106 (e.g. expandable wall 26 taught by Urich) prevents the external sheath 102 from collapsing, multiple sheaths would provide additional protection against collapse of the outer sheath, thus it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Mackool so as to further comprise a plurality of expandable walls molded in a spaced apart relation within said sheath. Further, it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to the limitation “molded in a spaced apart relation”, such limitation constitutes product-by-process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 24:** The expandable wall 26 taught by Urich and Dillon is comprised of silicone walls, an elastomeric material, and is thus elastic. The sheath 102 taught by Mackool is also silicone and is thus also formed from an elastic material. The said expandable walls fairly suggested by Urich and Dillon and Mackool are thus elastic. Mackool shows in Fig. 9 an inner sheath 108 that is relatively thin compared with the thickness of the sheath 102. Thus the combined teaching of Urich and Dillon and Mackool fairly suggest an inner sheath, or expandable wall, that is relatively thin compared with the thickness of an outer sheath, such as sheath 102. The motivation to combine the teachings of Urich and Dillon and Mackool is stated *supra* with respect to claim 18.

7. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814) as applied to claims 1-4 and 14-17 above, and further in view of Sepielli (U.S. Patent No. 5,554,894).

With respect to **claim 29:** Urich teaches an ocular surgical system for performing ocular surgery on an eye, comprising: a surgical instrument 11 considered herein to be a handpiece inasmuch as Urich teaches that the instrument 11 has a tip 12 for insertion into the cornea for use in a known emulsification procedure that cannot be accomplished with a non-handheld device. The system includes an irrigation lumen in the form of sleeve 14; a fluid supply 18; an irrigation line

16 interconnecting said fluid supply 18 and said irrigation lumen 14; and a tubular member in the form of surge suppresser 24 disposed along said aspiration line 20 and in fluid communication with an aspiration line 20 and an aspiration lumen in the form of an inner channel (not shown) within tip 12. Tubular member 24 has a collapsible flexible wall 26, which is considered herein to also be expandable due to its flexibility. The tubular member 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid to enhance flow of fluid into said irrigation lumen upon clearing of the occlusion, inasmuch as “configured to” is interpreted as meaning “capable of”. That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (Col. 2, lines 25-37)

Urich does not teach that the tubular member 24 is disposed along said irrigation line 16 as part of and in fluid communication with said irrigation line 16 and said irrigation lumen 14. However, Urich teaches that the flow-limiting device of said tubular member prevents a surge of flow of aspiration that could result in excessive vacuum pressure at the surgery site and potential collapse of the anterior chamber of the eye. Dillon teaches that it is known that changes to the partial pressure of oxygen in the eye is a hazard to lens transparency and can cause cataracts. Thus, since the device of Urich is used in intraocular surgeries to remove cataracts, it would be obvious to one of ordinary skill in the art to modify the device of Urich such that a flow-limiting member is disposed along the irrigation line as part of and in fluid communication with said irrigation line and said irrigation lumen to prevent excessive flow of irrigation solution to the surgery site as taught by Dillon. (‘814, ¶0053)

Neither Urich nor Dillon teaches that the handpiece 11 is driven by a controller in the form of a control system having housing 103 through a power line. Sepielli teaches a footswitch 101 for controlling a surgical phacoemulsification handpiece for ophthalmic surgery that is connected to said handpiece via a power line in the form of cable 115 having connector 123. (Col. 4, lines 15-19) Sepielli teaches that the footswitch supplies power to the handpiece remotely and allows the surgeon to adjust the power settings or preset patterns remotely via switches 105,107,109,111 and a touch-screen display 133, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon such that handpiece 11 is driven by a controller through a power line as taught by Sepielli to provide a means for remotely powering and controlling the handpiece to prevent unnecessary interruption of surgery for adjustment. ('894, Col. 3, lines 28-38)

With respect to **claim 30:** The tubular member 24 taught by Urich is disposed proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. ('448, Col. 1, lines 10-14, Col. 4, lines 43-45)

With respect to **claim 31:** The tubular member 24 taught by Urich is disposed in parallel fluid communication with said irrigation line 16 and irrigation lumen 14. ('448, Fig. 1)

With respect to **claim 32:** The tubular member wall 26 taught by Urich is formed from silicone, an elastomeric material, which is an elastic material. ('448, Col. 2, lines 41-44)

8. Claims 33, 35 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Dillon (U.S. Patent Application Publication No. 2004/0229814) and further in view of Sepielli (U.S. Patent No. 5,554,894) as applied to claims 29-32 above, and further in view of Mackool (U.S. Patent No. 5,084,009).

With respect to **claim 33:** The combined teaching of Urich and Dillon and Sepielli does not teach a sheath disposed around an expandable elastic wall, e.g. wall 26 taught by Urich. Mackool teaches a phacoemulsification (hereafter, “phaco”) needle 106 having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle 106. Mackool teaches that the inner sheath 108 prevents the outer silicone sheath from collapsing onto the phaco needle, therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Sepielli such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12. The tubular member of the combined teaching of Urich and Dillon and Sepielli and Mackool comprises a sheath such as external sheath 102 taught by Mackool, disposed around an expandable wall such as wall 26 taught by Urich. (‘009, Col. 5, lines 48-57, col. 6, lines 1-5)

With respect to **claim 35:** The sheath of the combined teaching of Urich and Dillon and Sepielli and Mackool is comprised of silicone (as taught by Mackool), which is a flexible material, as Mackool teaches that the silicone sheath 102 collapses. Thus, the sheath is flexible. The motivation to combine the teachings of Urich and Dillon and Sepielli and Mackool is stated *supra* with respect to claim 33.

With respect to **claim 37:** With regard to the limitation “the sheath and expandable wall are integrally molded”, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable over the prior art of Urich and Dillon and Sepielli and Mackool even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 38:** The device of Urich and Dillon and Sepielli and Mackool does not explicitly teach a further comprising a plurality of expandable walls molded in a spaced apart relation within said sheath. However, since Mackool teaches that the inner sheath 106 (e.g. expandable wall 26 taught by Urich) prevents the external sheath 102 from collapsing, multiple sheaths would provide additional protection against collapse of the outer sheath, thus it would be obvious to one of ordinary skill in the art to modify the device of Urich and Dillon and Mackool so as to further comprise a plurality of expandable walls molded in a spaced apart relation within said sheath. Further, it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977)

With respect to the limitation "molded in a spaced apart relation", such limitation constitutes product-by-process claim language. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

With respect to **claim 39:** The expandable wall 26 taught by Urich and Dillon is comprised of silicone walls, an elastomeric material, and is thus elastic. The sheath 102 taught by Mackool is also silicone and is thus also formed from an elastic material. The said expandable walls fairly suggested by Urich and Dillon and Sepielli and Mackool are thus elastic. Mackool shows in Fig. 9 an inner sheath 108 that is relatively thin compared with the thickness of the sheath 102. Thus the combined teaching of Urich and Dillon and Sepielli and Mackool fairly suggests an inner sheath, or expandable wall, that is relatively thin compared with the thickness of an outer sheath, such as sheath 102. The motivation to combine the teachings of Urich and Dillon and Sepielli and Mackool is stated *supra* with respect to claim 33.

9. Claims 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urich (U.S. Patent No. 7,083,591) in view of Mackool (U.S. Patent No. 5,084,009).

With respect to **claim 41:** Urich teaches an accumulator in the form of surge suppressor 24 defining an accumulator chamber 28 for an ocular surgical handpiece 11, comprising: a tubular portion 24 comprising an expandable elastic wall 26 inasmuch as the wall is made from an elastomeric material which imparts elastic capability. The accumulator 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid to enhance flow of fluid into an aspiration lumen upon clearing of the occlusion, inasmuch as “configured to” is interpreted as meaning “capable of”. That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (‘448, Col. 2, lines 25-37)

Urich does not teach a sheath disposed around the expandable elastic wall of the tubular member 24. Mackool teaches a phacoemulsification (hereafter, “phaco”) needle having an external silicone infusion sheath 102 and an internal sheath 108 surrounding the phaco needle. Mackool teaches that the inner sheath 108 prevents the outer silicone sheath from collapsing onto the phaco needle. therefore it would be obvious to one of ordinary skill in the art to modify the device of Urich such that the existing infusion sleeve 14 defining the infusion lumen serves as an inner sheath preventing a second, flexible outer sheath such as that taught by Mackool from collapsing onto said needle 14,12.

With respect to **claims 42,44:** With regard to the limitation “the sheath and expandable wall of the device are integrally molded”, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) The device of the combined teaching of Urich and Mackool meets the limitation of a sheath disposed around an expandable wall, thus rendering the limitation “the sheath and expandable wall of the device are integrally molded” obvious.

With respect to **claim 43:** Urich teaches an infusion source for a ocular surgery having a needle in the form of infusion sleeve 14 having sharp tip 12 mounted coaxially therein with at least an irrigation lumen defined by the inner wall of sleeve 14 comprising a fluid supply in the form of gravity bottle 18 (Col. 2, lines 14-23); an irrigation line 16 interconnecting said fluid supply 18 and said irrigation lumen defined by sleeve 14 (Col. 4, lines 21-23). Urich teaches an accumulator in fluid communication with the irrigation line inasmuch as fluid pressure from the irrigation line 16 is capable of causing a pressure gradient in aspiration line 20. The accumulator is present in the form of a surge suppressor 24 defining an accumulator chamber 28 for an ocular surgical handpiece 11, comprising: an tubular member 24 comprising an expandable elastic wall 26 inasmuch as the wall is made from an elastomeric material which imparts elastic capability. The accumulator 24 defines an accumulator chamber 28 and is configured to expand upon accumulation of fluid to enhance flow of fluid into an aspiration lumen upon clearing of the occlusion, inasmuch as “configured to” is interpreted as meaning “capable of”. That is, the limitation of expanding upon accumulation of fluid flows inherently and necessarily from the teachings of Urich regarding an expandable tubular member. (‘448, Col. 2, lines 25-37)

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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